

|   |                        |              |            |
|---|------------------------|--------------|------------|
| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br>( Not for submission under 37 CFR 1.99) | Application Number     |              | 10565401   |
|   | Filing Date            |              | 2006-01-20 |
|   | First Named Inventor   | Gary P. Cook |            |
|   | Art Unit               | 1615         |            |
|   | Examiner Name          | S. Tran      |            |
|   | Attorney Docket Number | 02181.0086U2 |            |

| U.S.PATENTS       |         |               |                        |            |   |  |
|-------------------|---------|---------------|------------------------|------------|---|--|
| Examiner Initial* | Cite No | Patent Number | Kind Code <sup>1</sup> | Issue Date | Name of Patentee or Applicant of cited Document | Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear |
|                   | 1       | 3865352       |                        | 1975-02-11 | Nelson et al                                    |  |
|                   | 2       | 4165219       |                        | 1979-08-21 | Huber   |  |
|                   | 3       | 5538739       |                        | 1996-07-23 | Bodmer et al                                    |  |
|                   | 4       | 6217893       |                        | 2001-04-17 | Pellet et al                                    |  |
|                   | 5       | 6740634       |                        | 2004-05-25 | Saikawa et al                                   |  |
|                   | 6       | 7388032       |                        | 2008-06-17 | Saikawa et al                                   |  |
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## **U.S.PATENT APPLICATION PUBLICATIONS**

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|-------------------|---------|--------------------|------------------------|------------------|---|--|
|                   | 1       | 20020142050        |                        | 2002-10-03       | Straub et al                                    |  |
|                   | 2       | 20020155158        |                        | 2002-10-24       | Lewis et al                                     |  |
|                   | 3       | 20070092574        |                        | 2007-04-26       | Cook  |  |

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## **FOREIGN PATENT DOCUMENTS**

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|-------------------|---------|--------------------------------------|---------------------------|------------------------|------------------|---|--|--------------------------|
|                   | 1       | WO1998032423                         |                           |                        | 1998-07-30       | Takeda Chemical Industries Ltd.                 |  | <input type="checkbox"/> |
|                   | 2       | WO2003092585                         |                           |                        | 2003-11-13       | PR Pharmaceuticals                              |  | <input type="checkbox"/> |
|                   | 3       | WO2004078147                         |                           |                        | 2004-09-16       | PR Pharmaceuticals                              |  | <input type="checkbox"/> |
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|--------------------|---------|---|--------------------------|
|                    | 1       | Mohr, W.D. et al., "Mixing in Laminar-Flow Systems," 1957, ACS, Industrial and Engineering Chemistry, Vol. 49, No. 11   | <input type="checkbox"/> |
|                    | 2       | Mott, Robert L., "Applied Fluid Mechanics," 1972, Charles E. Merrill Publishing   | <input type="checkbox"/> |
|                    | 3       | Smith et al., "Evaluation of poly(lactic acid) as a biodegradable drug delivery system for parenteral administration," Intl. J. Pharm. 30:215-220, 1986   | <input type="checkbox"/> |
|                    | 4       | Harnby et al. editors, "Mixing in the Process Industries," 1992, BUTTERWORTH & HEINEMANN; Second Edition, Chapter 12; Godfrey JC, "Static Mixers"   | <input type="checkbox"/> |
|                    | 5       | Rothen-Weinhold et al., "Development and evaluation in vivo of a long-term delivery system for vapreotide, a somatostatin analog," 1998, J. Contr. Rel. 52  | <input type="checkbox"/> |
|                    | 6       | Rothen-Weinhold et al., "Stability studies of a somatostatin analogue in biodegradable implants," 1999, Intl. J. Pharm. 178   | <input type="checkbox"/> |
|                    | 7       | Maa, Y.F. and Hsu, C., "Liquid-Liquid emulsification by static mixers for use in microencapsulation," 1996, Taylor & Francis, Journal of Microencapsulation, Vol. 13, No. 4   | <input type="checkbox"/> |
|                    | 8       | Crooks, Richard M. & Seong, Gi Hun, "Efficient Mixing and Reactions within Microfluidic Channels Using Microbead-Supported Catalysts," 2002, ACS, Journal of the American Chemical Society, Vol. 124, No. 45  | <input type="checkbox"/> |
|                    | 9       | Yanai et al., "Optimal Formulation of an Angiogenesis Inhibitor, TNP-470, for Arterial Injection Determined by In Vitro Drug Release and Stability, and In Vivo Activity," International Journal of Pharmaceuticals 123 (1995)                                  | <input type="checkbox"/> |

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|    |   |                          |
|----|---|--------------------------|
| 10 | Edlund and Albertson, "Degradable polymer microspheres for controlled drug delivery," In: Advances in Polymer Science, Abe et al. Ed., Springer-Verlag, Heidelberg, 2002, discloses many different methods for preparing microparticles | <input type="checkbox"/> |
| 11 | Office Action dated February 12, 2010 from State Intellectual Property Office of the Peoples Republic of China Application No. 2004800008408.8  | <input type="checkbox"/> |
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